No. 17-290

IN THE

Supreme Court of the United States

MERCK SHARP & DOHME CORP.,

Petitioner,

v.

DORIS ALBRECHT, et al.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq., preempts a state-law failure-to-warn claim when the Food and Drug Administration has rejected the brand-name drug manufacturer's application, which included all relevant scientific data, to change its drug's label to warn about the very risk underlying the claim.

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INTEREST OF *AMICUS CURIAE*[*]

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters in all 50 states. WLF promotes and defends free enterprise, individual rights, limited government, and the rule of law. Since its founding in 1977, WLF has appeared as *amicus curiae* in important preemption cases, urging the Court to ensure that federal law operates efficiently and uniformly—as Congress intended. *See, e.g., ONEOK, Inc. v. Learjet, Inc.*, 135 S. Ct. 1591 (2015); *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013); *Wyeth v. Levine*, 555 U.S. 555 (2009).

WLF believes that individual freedom, the American economy, and public health all suffer when state law, including state tort law, interferes or conflicts with federal regulatory regimes, including the Federal Food, Drug, and Cosmetic Act (FDCA) 21 U.S.C. § 301, et seq. Conflicting federal and state duties are not merely inefficient; they make it impossible for regulated parties to comply with both state and federal law without incurring serious liability.

The Supremacy Clause prevents state law from imposing that Hobson's choice on anyone. But the decision below, by denying federal preemption in the face of clear impossibility, would render the Supremacy Clause a dead letter.

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[*] No party's counsel authored any part of this brief. No person or entity, other than WLF and its counsel, helped pay for the preparation or submission of this brief. All parties have consented to the filing of WLF's brief.

STATEMENT OF THE CASE

In 1995, the FDA approved the prescription drug Fosamax for treating osteoporosis in older women. Pet. App. 5a, 12a. Over the next 15 years, published studies suggested a possible link between long-term Fosamax use and atypical femoral fractures. *Id.* at 13a-14a. Merck, Fosamax's manufacturer, alerted the FDA to these studies. *Id.* at 13a. In June 2008, the FDA asked Merck to submit all available information it had linking the use of bisphosphonates to femoral fractures. *Id.* at 14a. Merck complied fully. *Ibid.*

In September 2008, Merck submitted a prior-approval supplement (PAS) seeking the FDA's permission to revise portions of Fosamax's label. Pet. App. 14a-15a. Under the Adverse Reactions section, Merck proposed adding "low-energy femoral shaft fracture" as a potential adverse reaction. *Id.* at 16a. Under the Warnings & Precautions section, Merck proposed adding a new subsection entitled "Low-Energy Femoral Shaft Fracture," which warned that "[l]ow-energy fractures of the subtrochanteric and proximal femoral shaft"—the upper and middle thigh bone—"have been reported in a small number of bisphosphonate-treated patients." *Id.* at 15a-16a. The proposed warning added that "some" of those fractures were "stress fractures * * * occurring in the absence of trauma." *Ibid.*

In April 2009, an FDA liaison instructed Merck to "hold off" on changing the Warnings & Precautions label until the FDA could "decide on language" for a stronger precaution "if it is warranted." Pet. App. 17a-18a. Then, in May 2009,

the FDA issued its Complete Response Letter, *id.* at 18a, which reflected "FDA's complete review of the data submitted" and described "all of the specific deficiencies" the agency identified. *See* 21 C.F.R. 314. 110(a)(1), (2). While the FDA agreed that Merck could add "low-energy femoral shaft and subtrochanteric fractures" to the Adverse Reactions section of the label, it rejected Merck's proposed changes to the Warnings & Precautions section. Pet. App. 18a-19a.

The FDA determined that "[i]dentification of 'stress fractures' may not be clearly related" to the "fractures that have been reported in the literature." Pet. App 18a-19a. In the FDA's view, any "[d]iscussion of the risk factors for stress fractures [was] not warranted and [was] not adequately supported by the available literature and post-marketing adverse event reporting." *Ibid.* Following the FDA's response, Merck promptly updated the Adverse Reaction section of Fosamax's label.

The FDA issued a safety announcement in March 2010. It confirmed that the available data still had "not shown a clear connection between bisphosphonate use and a risk of atypical subtrochanteric femur fractures." Pet. App. 19a. In fact, no study had shown "even that Fosamax use was definitely associated with atypical fractures." *Id.* at 13a. So the FDA commissioned a task force to gather more information. *Ibid.*

In September 2010, the FDA's task force reported an "association" between atypical femoral fractures and long-term bisphosphonate use. Pet App. 121a. But the task force found nothing "proven

to be causal." *Ibid.* In response, the FDA announced that even though causation was "still not clear," the agency would begin "considering label revisions." *Id.* at 20a-21a.

In October 2010, the FDA directed bisphosphonate manufacturers to revise the Warnings & Precautions sections of their labels to disclose the risk of atypical femoral fractures. Pet. App. 21a. Even if such fractures were "potentially more closely related to" long-term use of bisphosphonates, the FDA still believed it was "not clear" whether bisphosphonates caused the fractures. *Ibid.* Nonetheless, upon obtaining clarification from the FDA, Merck added the FDA's approved language to the Warnings & Precautions section of Fosamax's label. *Id.* at 21a-23a.

After the FDA approved Fosamax's revised label, more than 1,200 Fosamax users who had allegedly suffered an atypical femoral fracture sued Merck for failing to warn of the risk of that injury. Pet. App. 23a. These lawsuits were combined in multi-district litigation (MDL) in the District of New Jersey. *Ibid.* Following a bellwether trial, the district court issued an opinion addressing Merck's impossibility-preemption defense. *Id.* at 25a.

Applying this Court's decision in *Wyeth v. Levine*, the district court found "clear evidence that the FDA would not have approved a change to the Precautions section of the Fosamax label" before the FDA's task force report. Pet. App. 168a. The district court then applied that preemption holding to all MDL cases in which the plaintiff's alleged injury occurred before September 14, 2010 (the date of the

FDA's task force report) and granted summary judgment to Merck in those cases. *Id.* at 152a.

The Third Circuit vacated and remanded. Pet. App. 1a-74a. The court announced that *Levine*, by requiring "clear evidence" that the FDA would refuse a label change before a state-law claim arising from that label will be preempted, imposed a burden of proof "synonymous with 'clear and convincing evidence.'" *Id.* at 37a. Under this heightened bar, a defendant must prove that it "is highly probable that the FDA would not have approved a change to the drug's label" to establish a preemption defense. *Ibid.*

According to the Third Circuit, that question—whether the FDA would have refused a label change—is strictly a question of fact for the jury. Pet. App. 38a-55a. "Because the [*Levine*] test requires the factfinder to speculate about hypothetical scenarios using inferences drawn from historical facts, reasonable jurors could reach a broad range of conclusions when confronted with this record." *Id.* at 67a-68a. The panel determined that "a reasonable jury applying a heightened standard of proof *could* conclude" that the FDA would have allowed the label change if Merck had worded it differently. *Id.* at 67a.

SUMMARY OF ARGUMENT

Under the Supremacy Clause, any conflicting state law must give way to federal law. This Court has recognized that complying with both federal and state law is "impossible" for drug manufacturers when "[i]t was not lawful under federal law for [them] to do what state law required of them."

PLIVA, Inc. v. Mensing, 564 U.S. 604, 618 (2011). This case is no exception.

The only way Merck could have avoided liability under New Jersey tort law would have been to strengthen Fosamax's label to warn of an increased risk of atypical femoral fractures. But Merck has shown decisively not merely that the FDA *would have* rejected a stronger Fosamax warning, but that the FDA *did* reject a stronger Fosamax warning. A "clearer" showing of impossibility preemption is hard to imagine.

True enough, under this Court's holding in *Wyeth v. Levine*, the FDA's mere approval of a brand-name label, standing alone, doesn't establish a federal ceiling for drug regulation. But *Levine* also makes clear that the FDA's formal rejection of a manufacturer's proposed shift to a stronger label does just that. Here, no one disputes that before the FDA's September 2010 task force report, federal law and New Jersey law imposed on Merck irreconcilable labeling duties. So under *Levine*'s reading of the Supremacy Clause, New Jersey's conflicting tort-law duty must give way to federal law.

But the Third Circuit disagrees. The panel below held that if a reasonable jury could find that the FDA would have approved a differently worded label than the one Merck proposed, the threshold legal question of preemption goes to the jury, not the court. In so holding, the appeals court invites a lay jury not only to second guess the FDA's labeling decision but also to speculate on a labeling decision the FDA *might* have made. That holding collides with this Court's preemption cases.

By focusing on what the FDA might have done rather than on what the FDA did, the decision below dilutes *Levine* beyond all recognition. As the United States has confirmed in its *amicus* brief, the FDA's rejection of Merck's proposed label turned solely on the available scientific data, not on Merck's choice of words. If the Court were to adopt the Third Circuit's view of conflict preemption on this record, it would render the Supremacy Clause "all but meaningless." *Bartlett*, 570 U.S. at 488. If, on the other hand, the Court does little more than apply *Levine* straightforwardly, the judgment below must be reversed.

Nor does any presumption against preemption apply here. In equating *Levine*'s "clear evidence" rule with a clear-and-convincing-evidence standard of proof, the panel below invoked the "presumption against preemption." Pet. App. 37a. But no basis exists in the Constitution for applying a presumption against preemption—in this or any other case. And nothing in logic supports such a presumption when, as here, preemption hinges on the existence of a genuine conflict between state and federal law. On the contrary, implied conflict preemption is the quintessential example of the Supremacy Clause at work.

ARGUMENT

I. RESPONDENTS' FAILURE-TO-WARN CLAIM IS PREEMPTED BECAUSE FEDERAL LAW PROHIBITED MERCK FROM PROVIDING A STRONGER WARNING.

Under the Supremacy Clause, state law that conflicts with federal law is "without effect." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). Even without an express preemption provision in the federal law, state law is impliedly preempted if it is "impossible for a private party to comply with both state and federal requirements." *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). That is this case. As shown below, because it was impossible for Merck to comply with New Jersey tort law without simultaneously violating federal law, any state-law liability premised on a failure to warn is fully preempted.

A. The Third Circuit's Holding Flouts This Court's Preemption Case Law.

1. The leading preemption precedent for brand-name drug manufacturers is *Wyeth v. Levine*. In *Levine*, a Vermont jury determined that Wyeth's "inadequate label" on its drug Phenergan failed to warn adequately "about the [gangrene] risks of IV-push administration" of that drug. 555 U.S. at 564. On appeal, Wyeth argued that the "FDA's approvals" of Phenergan's label provided it "with a complete defense to Levine's tort claims." *Id.* at 558-59.

The Court disagreed. While recognizing that "the FDA retains authority to reject labeling

changes," *Levine* emphasized that, under the FDCA, brand-name drug manufacturers are generally free to strengthen their drugs' labels when necessary. *Id.* at 571. The Court held that, "absent clear evidence that the FDA would not have approved a change to Phenergan's label," it could "not conclude that it was impossible for Wyeth to comply with both federal and state requirements." *Id.* at 572. Put another way, while the FDA's mere approval of a brand-name label does not, as Wyeth contended, establish a federal "ceiling for drug regulation," *id.* at 573, the FDA's denial of a manufacturer's requested label change would do precisely that.

Nor is that all. As this Court later clarified in *PLIVA v. Mensing*, a plaintiff's rank speculation about whether and how a drug manufacturer *might* have reconciled its federal and state-law duties is never enough to defeat preemption. In *Mensing*, the generic manufacturers argued that any state-law duty to strengthen their drug's label conflicts with their "ongoing federal duty of 'sameness,'" which requires a generic drug's label to "be the same as the [brand-name] drug product's labeling." 564 U.S. at 613. But the plaintiffs argued that the generic manufacturers' independent duty to alert the FDA to any newly discovered risks for their drugs made it "certainly possible" that the FDA would have approved a "safer label" had the manufacturers bothered to ask for one. *Id.* at 618-20.

Rejecting that argument, the Court held that it was "impossib[le]" for generic manufacturers to honor both their state and federal duties. *Ibid.* Because preemption hinges on "whether the private party could independently do under federal law what

state law requires of it," the plaintiffs' mere "conjectures" would not "suffice to prevent federal and state law from conflicting for Supremacy Clause purposes." 564 U.S. at 621. In other words, the preemption analysis "should not involve speculation about ways in which federal agencies and third-party actions could potentially reconcile federal duties with conflicting state duties." *Id.* at 623 (plurality op.).

This Court applied the above preemption principles to design-defect claims in *Mutual Pharmaceutical Co. v. Bartlett*. There, to avoid design-defect liability under New Hampshire law, drug manufacturers had to either design a safer drug or add a stronger warning to the label. 570 U.S. at 482-83. The plaintiff argued that, at the very least, the defendant generic manufacturer could comply with both federal and state law by simply pulling its drug from the New Hampshire market altogether. *Ibid.* The Court disagreed.

Bartlett concluded that accepting the plaintiff's argument would render impossibility preemption "all but meaningless." *Id.* at 488. That is because federal law prevented the generic manufacturer from either redesigning the drug or strengthening the label. And because federal law "prohibited" the "remedial action required to avoid liability" under New Hampshire law, the plaintiff's design-defect claim was preempted. *Id.* at 486. Above all, this Court's "preemption cases presume that an actor seeking to satisfy both his federal and state-law obligations is not required to cease acting altogether in order to avoid liability." *Id.* at 488.

As the record here shows, the FDA rejected the very label Merck needed to avoid state tort liability. And it is the FDA, not the states, that Congress gives the final statutory and regulatory authority to determine a drug's label. But a state-law duty to provide a warning that the FDA has already rejected is a duty to misbrand drugs in violation of federal law. Under these facts, any liability that arises from breaching such a state-law duty is preempted under the Supremacy Clause.

2. In the face of this Court's preemption precedents, the respondents argue that the FDA might have approved a stronger Fosamax warning if only Merck had worded its supplement application differently. The Third Circuit agreed, assuming that a reasonable jury "could find it less than highly probable" that the FDA would have rejected a differently phrased warning about atypical femoral fractures. Pet. App. 56a-57a. According to the appeals court, the "question for preemption purposes is whether the FDA would have approved a different label amendment than the one it actually rejected in the May 2009 letter." *Id.* at 52a.

But Merck's PAS submission must be viewed "in its entirety, not distorted as an exercise in disjointed parsing." *In re Sawyer*, 360 U.S. 622, 653 (1959) (Frankfurter, J., dissenting). That is, "[w]e must think things, not words, or at least we must constantly translate our words into facts for which they stand, if we are to keep to the real and the true." Oliver Wendell Holmes, Jr., *Law in Science and Science in Law*, 12 Harv. L. Rev. 443, 460 (1889). Here, the FDA's outright rejection of Merck's label supplement with no haggling over its wording

shows that the FDA believed *no* additional warning was appropriate at that time.

And contrary to the respondents' claim, nothing in *Levine* "impos[es] upon [a] drug manufacturer a duty to continually 'press' an enhanced warning which has been rejected by the FDA." *Dobbs v. Wyeth Phram.*, 797 F. Supp. 2d 1264, 1279 (W.D. Okla. 2011). In all events, the relevant question for preemption purposes isn't whether Merck could have asked for a differently worded warning, but whether the FDA would have approved one. *Levine*, 555 U.S. at 618-20. On that crucial point, there is no need for guesswork.

"If a warning is warranted, FDA will attempt promptly to identify easily corrected deficiencies in the proposed text and will then develop final labeling text with the manufacturer in an iterative process." U.S. Cert. Br. 21; *see* 21 C.F.R. 314.102(b). As the United States has confirmed, and the FDA's Complete Response Letter made clear at the time, the FDA rejected Merck's proposed warning "based on the agency's determination that the data was then insufficient to justify such a warning." U.S. Cert. Br. 22. Allowing a jury to second guess that decision based on semantics "would exert an extraneous pull on the scheme established by Congress." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001).

Levine's discussion of the history of Phenergan's label confirms that the Court understood its "clear evidence" standard as one that manufacturers could plausibly meet under an appropriate set of facts. Although the record in

Levine lacked such facts, they are present here—in spades. In contrast, the Third Circuit's rule sets the "clear evidence" bar so high that drug manufacturers can't possibly meet it even with a "smoking gun" rejection letter from the FDA. Pet. App. 55a.

If a plaintiff's counterfactual speculation about alternative wording can defeat impossibility preemption, brand-name drug manufacturers will leave nothing to chance. They will "have an incentive to submit a deluge of information that the [FDA] neither wants nor needs, resulting in additional burdens on the FDA's evaluation" of a label's adequacy. *Buckman*, 531 U.S. at 351. Under such a preemption regime, the FDA will be forced to divert precious time and resources to responding to manufacturers' futile, inexhaustibly worded label-change requests, rather than protecting the public health.

By focusing on what the FDA might have done rather than on what the FDA did, the Third Circuit's rule dilutes *Levine* beyond recognition. If the Court were to adopt this view of conflict preemption, it would render the Supremacy Clause "all but meaningless." *Mensing*, 564 U.S. at 621. At the same time, if the rationale for this Court's holding in *Levine* is to remain viable, the judgment below must be reversed.

B. None of *Levine*'s Case-Specific Barriers to Preemption Apply Here.

Like many conflict-preemption cases, *Levine* turned on its own sui generis facts. In denying preemption to Wyeth, the manufacturer of

Phenergan, the Court stressed that (1) Wyeth never advised the FDA of the dangers of administering Phenergan by the IV-push method; (2) Wyeth never tried to change Phenergan's label to warn of those dangers; (3) scant record evidence suggested that the FDA would have rejected a stronger warning label for Phenergan; and (4) the FDA never rejected a stronger warning. *None* of those fact-bound barriers to preemption exists here.

1. This case differs from *Levine* in many crucial respects. In *Levine*, for example, Wyeth did not even "argue that it supplied the FDA with an evaluation or analysis concerning the specific dangers posed by the IV-push method." 555 U.S. at 572-73. If anything, neither Wyeth nor the FDA "gave more than passing attention to the issue." *Id.* at 563.

Compare that "sparse correspondence," *id.* at 561, with Merck's detailed back-and-forth Merck with the FDA here. After published studies began suggesting a possible link between long-term Fosamax use and atypical femoral fractures, Merck immediately "submitted a comprehensive safety update" to the FDA. Pet. App. 13a-14a. And when the FDA asked Merck for all available information linking the use of bisphosphonates to such fractures, Merck complied fully. *Id.* at 14a.

Unlike in *Levine*, it is "undisputed that the FDA was aware of the possible link between Fosamax and atypical fractures well before September 2010." *Id.* at 60a. Yet because the "conflicting nature of the literature d[id] not provide a clear path forward," the FDA needed "more time"

to consider "the issue of a precaution." *Id.* at 59a-60a.

2. Nothing in *Levine*'s record suggested that Wyeth "had 'earnestly attempted' to strengthen [Phenergan's] intra-arterial injection warning." 555 U.S. at 561. Though Wyeth proposed language to warn of the risks of injecting Phenergan intra-arterially, "the FDA did not regard the proposed warning as substantively different." *Id.* at 573 n.5. In other words, Wyeth's "proposed warning was different, but not stronger." *Ibid.*

At bottom, Wyeth didn't "argue that it attempted to give the kind of warning required by the Vermont jury but was prohibited from doing so by the FDA." *Id.* at 572. For that reason, as the United States has explained, *Levine* "did not resolve how to determine the meaning and effect of an actual FDA labeling-supplement decision" because Wyeth never proposed, and the FDA never rejected, a stronger warning. U.S. Cert. Br. 23.

Not so here. Merck didn't even wait for the FDA to fully analyze the available data before acting. As Merck's PAS submission makes clear, Merck formally asked the FDA for permission to change Fosamax's label in September 2008. Relying on nine articles and an analysis of femoral fractures in Fosamax users, Merck emphasized the importance of "includ[ing] an appropriate statement" on the label to "increase physicians' awareness of possible fractures * * * and [to] allow early intervention." Pet. App. 15a.

In particular, Merck proposed adding, under the Adverse Reactions section of Fosamax's label, "low-energy femoral shaft fracture" as a potential adverse reaction. *Id.* at 16a. Under the Warnings & Precautions section, Merck proposed adding a new subsection entitled "Low-Energy Femoral Shaft Fracture," which warned that "[l]ow-energy fractures of the subtrochanteric and proximal femoral shaft have been reported in a small number of bisphosphonate-treated patients." *Id.* at 15a-16a.

As the record shows, Merck did everything in its power to obtain the FDA's approval for a stronger warning label. That fact alone distinguishes this case from *Levine*.

3. *Levine* hinged on the "absen[ce of] clear evidence that the FDA would not have approved a change to Phenergan's label." 555 U.S. at 571. Though Wyeth "suggest[ed] that the FDA intended to prohibit it from strengthening the [label]," it provided little evidence of that intention. As a result, "both the trial court and the Vermont Supreme Court rejected [Wyeth's contention] as a matter of fact." *Id.* at 572.

In contrast here, Merck has adduced ample evidence that the FDA would not approve a change to Fosamax's label. Confronted with Merck's data, FDA made clear that any "[d]iscussion of the risk factors for stress fractures [was] not warranted and [was] not adequately supported by the available literature and post-marketing adverse event reporting." Pet. App 18a-19a. The agency's March 2010 safety announcement reiterated that the available data still had "not shown a clear

connection between bisphosphonate use and a risk of atypical subtrochanteric femur fractures." *Id.* at 19a.

And unlike the factfinder in *Levine*, the district court explicitly found that "the FDA would not have approved a change to the Precautions section of the Fosamax label." *Id.* at 168a. Neither the Third Circuit nor the respondents contested any of the "undisputed" facts supporting that finding. *Id.* at 47a.

4. In *Levine*, the FDA "had not made an affirmative decision" to reject a stronger warning for Phenergan. 555 U.S. at 572. The record "lack[ed] any evidence that the FDA set a ceiling on this matter." *Id.* at 561. But here no one disputes that the FDA affirmatively rejected Merck's attempt to strengthen its Fosamax label.

While the FDA agreed that Merck could add "low-energy femoral shaft and subtrochanteric fractures" to the Adverse Reactions section of the label, it expressly rejected Merck's proposed changes to the Warnings & Precautions section. Pet. App. 18a-19a. An FDA liaison instructed Merck to "hold off" on changing the Warnings & Precautions label until the FDA could "decide on language" for a stronger precaution "if it is warranted." *Id.* at 17a-18a. As the district court put it, the record "provide[s] clear evidence that the FDA *would* have rejected a stronger Precautions warning because the FDA *did* reject a stronger Precautions warning." Pet. App. 150a.

Unlike *Levine*, this record leaves no doubt that the FDA both considered and rejected the very

warning that is the basis for the respondents' failure-to-warn claim. That isn't a distinction without a difference; it is a dispositive fact that singlehandedly answers the question presented.

II. No Presumption Against Preemption Applies Here.

In equating *Levine*'s "clear evidence" requirement with a clear-and-convincing-evidence standard of proof, the panel below invoked the "presumption against preemption." Pet. App. 37a (citing *Levine*, 555 U.S. at 571-73, 565 n.3). But that presumption has no bearing here. In fact, as shown below, *no* presumption attaches when deciding whether state law conflicts with federal law.

1. No basis exists in the Constitution for applying a presumption against preemption—in this or any other case. As "a matter of constitutional structure, there should be no systematic presumption against or in favor of preemption." Viet D. Dinh, *Reassessing the Law of Preemption*, 88 Geo. L.J. 2085, 2092 (2000). The Supremacy Clause makes Congress's lawful enactments "the supreme Law of the Land[,] * * * any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

That concluding phrase—"any Thing in the Constitution or Laws of any State to the Contrary notwithstanding"—is a classic *non obstante* provision. In the 18th century, legislatures used *non obstante* provisions "to specify that they did not want courts distorting the new law to accommodate the old." *Mensing*, 564 U.S. at 621-22 (plurality opinion).

The Supremacy Clause's *non obstante* provision "indicates that a court need look no further than 'the ordinary meanin[g]' of federal law, and should not distort federal law to accommodate conflicting state law." *Id.* at 623 (plurality opinion) (quoting *Levine*, 555 U.S. at 588) (Thomas, J., concurring in judgment). By going beyond the "ordinary meaning," the presumption against preemption distorts federal law. *See* Caleb Nelson, *Preemption*, 86 Va. L. Rev. 225, 304 (2000).

Nor is any such presumption required "to defend state interests from undue infringement." *Geier v. Am. Honda Motor. Co.*, 529 U.S. 861, 907 (2000) (Stevens, J., dissenting). After all, "[i]f a power is delegated to Congress in the Constitution, the Tenth Amendment expressly disclaims any reservation of that power to the States." *New York v. United States*, 505 U.S. 144, 156 (1992). Put differently, the Constitution itself resolves the inherent tension between federal and state power with a straightforward, self-executing rule: federal law trumps conflicting state law.

2. A presumption against preemption is also ahistorical. There is "no significant support in constitutional history for the conclusion that the [F]ramers intended any such presumption to be read into Article VI, clause 2." Martin R. Scordato, *Federal Preemption of State Tort Claims*, 35 U.C. Davis L. Rev. 1, 30 (2001).

On the contrary, the Framers adopted the Supremacy Clause precisely "to remedy one of the chief defects in the Articles of Confederation, by instructing courts to resolve state-federal conflicts in

favor of federal law." David Sloss, *Constitutional Remedies for Statutory Violations*, 89 Iowa L. Rev. 355, 402 (2004). By design, the Supremacy Clause "invalidates" any "interfer[ing]" or "contrary" state law. *Hillsborough Cnty., Fla. v. Automated Med Labs., Inc.*, 471 U.S. 707, 712 (1985) (internal citations and quotations omitted).

Nor does the presumption against preemption enjoy a long pedigree. *See, e.g.*, Mary J. Davis, *Unmasking the Presumption in Favor of Preemption*, 53 S.C. L. Rev. 967, 974 (2002) (showing that the Court's earlier preemption cases "resulted in almost automatic preemption of concurrent state regulation"). On the contrary, it wasn't until the 1980s that the presumption first arose in field preemption cases "as a possible reaction to the [federal government's] significant and ever-widening control over so many aspects of our daily lives." *Id.* at 1013. But for most of its history, "the Court has consistently applied implied preemption doctrine broadly to support a finding of preemption." *Ibid.*

3. Nothing in logic supports a presumption against preemption in cases—such as this one—where preemption hinges on the existence of a conflict between state and federal law. Instead, every reason exists to presume that Congress always wishes to preempt state law that conflicts with federal law. "Why," after all, "would Congress not have wanted ordinary pre-emption principles to apply where an actual conflict with a federal objective is at stake?" *Geier*, 529 U.S. at 870. If courts must presume otherwise, "state law could impose legal duties that would conflict directly with

federal regulatory mandates." *Ibid.* That can't be right.

This Court has recently abolished any "presumption against preemption" in express-preemption cases. In *Puerto Rico v. Franklin-California-Tax-Free Trust*, the Court held that when a "statute 'contains an express pre-emption clause,' we do not invoke any presumption against pre-emption." 136 S. Ct. 1938, 1946 (2016) (quoting *Chamber of Commerce of the United States v. Whiting*, 563 U.S. 582, 594 (2011)). Instead, the Court simply "'focus[es] on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'" *Ibid.*

But a presumption against preemption makes even less sense in conflict-preemption cases. Perhaps that is why the Court has openly questioned whether the presumption should ever apply in conflict-preemption cases. *See, e.g., Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 374 n.8 (2000) ("We leave for another day a consideration in this [implied preemption] context of a presumption against preemption."); *United States v. Locke*, 529 U.S. 89, 108 (2000) ("No artificial presumption [against preemption] aids us."). And some members of the Court have already answered "no." *See, e.g., Mensing*, 564 U.S. at 622 (Thomas, J.) (plurality opinion) (explaining that, if anything, "federal law should be understood to impliedly repeal conflicting state law").

Conflict preemption is the quintessential example of the Supremacy Clause at work. When a true federal-state conflict exists, preemption is

"inescapable and requires no inquiry into congressional design." *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963). That is because "*any* state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield." *Felder v. Casey*, 487 U.S. 131, 138 (1988) (emphasis added); *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982) ("[S]tate law is nullified to the extent that it actually conflicts with federal law.").

Under the Supremacy Clause, "the relative importance to the State of its own law is not material when there is a conflict with a valid federal law." *Ibid.* (internal citations and quotations omitted). And because the scope of the conflict itself delineates the scope of preemption, "a narrow focus on Congress's intent to supersede state law is misdirected." *City of New York v. FCC*, 486 U.S. 57, 64 (1988).

As the Eleventh Circuit has noted, "it is difficult to understand what a presumption in conflict preemption cases amounts to, as we are surely not requiring Congress to state expressly that a given state law is preempted using some formula or magic words." *Fla. State Conference of the NAACP v. Browning*, 522 F.3d 1153, 1168 (11th Cir. 2008). Nor is federal law "obliged to bend over backwards to accommodate contradictory state laws, as should be clear from the Supremacy Clause's blanket instruction." *Ibid.*

4. Even when the Court has applied the presumption against preemption, it has done so

inconsistently. True, in many cases when the Court's majority finds no preemption, it will invoke the presumption. *See, e.g., Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005) (finding that federal law regulating pesticides doesn't preempt state statutory and common-law claims); *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (finding that the FDCA's manufacturing and labeling requirements for medical devices don't preempt state common-law claims).

But just as often, when the Court finds state law preempted, the presumption vanishes without a trace. *See, e.g., Arizona v. United States*, 567 U.S. 387 (2012) (preempting Arizona's efforts at cooperative enforcement of federal immigration law); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) (preempting New York's common-law claims under the FDCA); *Geier*, 529 U.S. at 906-07 (Stevens, J., dissenting) ("[T]he Court simply ignores the presumption [against preemption].").

In other words, the Court "continues to simultaneously repeat and ignore the presumption against preemption." Calvin R. Massey, *Joltin' Joe Has Left and Gone Away: The Vanishing Presumption Against Preemption*, 66 Alb. L. Rev. 759, 764 (2003). But a legal presumption the Court can wield or withold as it pleases is little more than a crude parlor trick. It is like preening before a funhouse mirror; what you see depends on where you stand. Above all, "the maintenance of a presumption against preemption" forces the Court "to treat essentially similar cases in very different manners." Scordato, *supra*, at 30-31.

What's more, the Court's invocation of the presumption has become increasingly erratic in recent years. For example, among the five preemption cases decided during the 2011 Term, *none* discussed the presumption against preemption. *See* Ernest A. Young, *"The Ordinary Diet of the Law": The Presumption Against Preemption in the Roberts Court*, 2011 Sup. Ct. Rev. 253, 331 (2012). Armed with so pliable a presumption, the Court can hardly help but act capriciously. And to the extent the Court "systematically favor[s] one result over another" when analyzing state and federal conflicts, it "risk[s] an illegitimate expansion of the judicial function." Dinh, *supra*, at 2092.

* * *

The Supremacy Clause speaks for itself. The Court "should not strain to find ways to reconcile federal law with seemingly conflicting state law." *Mensing*, 564 U.S. at 622. The petitioner deserves to have its preemption defense evaluated on the best available evidence of an actual conflict rather than on a presumption that bears no apparent relation to that question. As it has done many times before, this Court should apply "ordinary," "longstanding," and "experience-proved principles of conflict preemption." *Geier*, 529 U.S. at 874. That analysis should be based on the substantive requirements of state and federal law—*not* on the expedient of some *a priori* rule of decision.

CONCLUSION

The Court should reverse the judgment below.

Respectfully submitted,

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